Docket Number EPA-HQ-OPP-2014-0576
www.regulations.gov

Triclopyr Preliminary Work Plan

Registration Review: Initial Docket Case Number 2710

December 2014

Approved by: Richard P Keigwin, Jr.

Richard P. Keigwin, Jr.
Director
Pesticide Re-evaluation Division

Date: 12-8-2014

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References:

This Preliminary Work Plan summarizes the Environmental Protection Agency's current position based on the following documents:

1. *Registration Review: Preliminary Problem Formulation for Environmental Fate and Ecological Risk, Endangered Species and Drinking Water Assessments for Triclopyr*. Montague, Brian and Liu, Larry. November 13, 2014.

2. *Triclopyr; Triclopyr, Triethylamine Salt (TEA); and Triclopyr, Butoxyethyl Ester (BEE). Human Health Assessment Scoping Document in Support of Registration Review*. Tyler, Jennifer; Perron, Monique M.; Venkateshwara, Lata. November 12, 2014.

3. *Triclopyr, salt and esters: Review of Human Incidents*. Evans, Elizabeth and Recore, Shanna. April 29, 2013.

4. *BEAD Chemical Profile (BCP) for Registration Review: Triclopyr Case*. March 13, 2014.

5. *Triclopyr Case Screening Level Usage Analysis (SLUA)*. April 19, 2013.

6. *Environmental Fate and Effects Division Spreadsheet: PC Codes: 116001, 116002, and 116004.* April 11, 2014.

7. *Health Effects Division Master Label Spreadsheet: PC Codes: 116001, 116002, and 116004.* May 16, 2014.

These and other supporting documents for the triclopyr registration review case may be found in the docket EPA-HQ-OPP-2014-0576 at http://www.regulations.gov.

OVERVIEW

The docket for the triclopyr acid and its salts and esters case is now open, initiating the first public comment period for this registration review (docket number EPA-HQ-OPP-2014-0576). This case includes the following active ingredients: triclopyr acid, triclopyr triethylamine salt (TEA), and triclopyr butoxyethyl ester. Triclopyr acid and its salts and esters (which will be collectively referenced to as triclopyr throughout the PWP) are systemic herbicides within the pyridine carboxylic acid chemical family registered for the control of a number of woody plant and weed species. They are registered for use on a number of agricultural crops including rice and for nonagricultural use on range and pasture land, forests, rights of way, on turf (commercial and homeowner), and numerous aquatic areas for aquatic weed control. This Preliminary Work Plan (PWP) document explains what EPA's Office of Pesticide Programs knows about triclopyr, highlighting anticipated data and assessment needs, identifying the types of information that would be especially useful to the Agency in conducting the review, and providing an anticipated timeline for completing the registration review for triclopyr.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders. The Agency intends, by sharing this information in the docket, to inform the public of what it knows about triclopyr and what types of new data or other information would be helpful for the Agency to receive as it moves toward a decision on triclopyr. The Agency encourages all interested stakeholders to review the PWP and Appendix and to provide comments and additional information that will help the Agency's decision-making process for this chemical. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP and Appendix about which the Agency specifically seeks comments and information. Interested stakeholders could include: environmental non-profit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, residential, and other users of pesticides; or the public at large.

The PWP begins by listing the anticipated data needs for triclopyr. Next, it discusses the statutory and regulatory authority for registration review. Then the document provides chemical facts, use and usage information, recent actions, the anticipated risk assessments, and a projected registration review timeline for triclopyr. Finally, the Appendix to this document includes identification and discussion of some areas that are considered generally in registration review along with some additional chemical case-specific information.

ANTICIPATED DATA NEEDS

Table 1 below summarizes anticipated data needs for triclopyr. For additional discussion of the anticipated data needs, see:

- *Registration Review; Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Triclopyr [Triclopyr Acid (PC Code 116001), Triclopyr Triethylamine Salt (PC Code 116002), and Triclopyr Butoxyethyl Ester (PC Code 116004)]*
- *Triclopyr; Triclopyr, Triethylamine Salt (TEA); and Triclopyr, Butoxyethyl Ester (BEE). Human Health Assessment Scoping Document in Support of Registration Review.*

Table 1: Anticipated Data Needs for the Triclopyr Registration Review

Guideline Number[1]	Study Title[1]	Test Material	Estimated Timeframe (Months from receipt of DCI)
Anticipated Data Needs for Triclopyr			
835.2240	Aqueous photolysis	TGAI (acid)	12
835.4200	Anaerobic soil metabolism	TGAI (acid, TEA, and BEE)	12
835.4300	Aerobic aquatic metabolism	TGAI (BEE)	12
835.4400	Anaerobic aquatic metabolism	TGAI (BEE)	12
850.1300	Freshwater invertebrate lifecycle	TGAI (BEE)	12
850.1350	Estuarine/marine invertebrate lifecycle	TGAI (BEE)	12
850.1730	Fish BCF	TGAI (BEE)	12
850.2100	Avian oral toxicity – Passerine	TGAI (acid)	12
870.3465	Subchronic (90-day) inhalation toxicity study	TGAI	12
860.1340	Residue analytical methods[2]	TGAI	12
875.2100	Turf transferable residue study	TEP	12
Non-GDLN (OECD Test Guideline 213)	Honey bee adult acute oral toxicity	TGAI (acid)	12

[1] On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 – Ecological Effects Tests – including renumbering and other designations or changes for some guideline studies. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028

[2] The results of a radio-validation study are needed to ensure the ability of the GC/MS method GRM97.02 to recover aged residues.

Table 1: Anticipated Data Needs for the Triclopyr Registration Review			
Guideline Number[1]	**Study Title[1]**	**Test Material**	**Estimated Timeframe (Months from receipt of DCI)**
Non-GDLN (OECD Test Guideline 237)	Honey bee larvae acute oral toxicity	TGAI (acid)	12
Non-GDLN	Honey bee adult chronic oral toxicity	TGAI (acid)	12
Non-GDLN	Honey bee larvae chronic oral toxicity	TGAI (acid)	12
Non-GDLN (OECD Test Guidance 75)	Semi-field testing for pollinators	TEP	24
Anticipated Data Needs for TCP Degradate			
850.1400	Fish Early Life Stage[3]	TCP	12

TGAI = technical grade active ingredient; TEP = typical end-use product

[3] Data requirement pending review of submitted study.

STATUTORY AND REGULATORY AUTHORITY

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided on EPA's website.[4]

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop a Final Work Plan (FWP) and anticipated schedule for the registration review of triclopyr.

CHEMICAL FACTS

Table 2 provides a summary of the chemical facts for triclopyr

Table 2: Chemical Facts for Triclopyr	
PC code	116001 (triclopyr), 116002 (triclopyr, triethylamine salt, TEA), 116004 (triclopyr, butoxyethyl ester, BEE)
Case Number	2710
CAS Number	57213-69-1, 57213-69-1, 64700-56-7
Year first registered	1979 (TEA), 1980 (BEE), 2005 (triclopyr)
Pesticide Type	Herbicide
Chemical class	Pyridine
Reregistration Eligibility Decision (RED)	October 1998
Tolerance Reassessment Eligibility Decision (TRED)	Not applicable. Tolerance reassessment was included in the RED.

[4] http://www.epa.gov/oppsrrd1/registration_review/

Table 2: Chemical Facts for Triclopyr	
Cumulative group	Not applicable. Triclopyr has not been identified as a member of a cumulative group that shares a common mechanism of toxicity
40 CFR Citation	Tolerances for triclopyr are established in 40CFR 180.417.
Dual-use	Triclopyr is registered for conventional pesticidal uses only and has no registered antimicrobial or biopesticidal uses.
Non-pesticidal uses	There are no identified non-pesticidal uses of triclopyr.
Pesticide Re-evaluation Division, Chemical Review Manager	Brittany Pruitt, pruitt.brittany@epa.gov, 703-347-0289
Registration Division, Product Manager	Kathryn Montague, montague.kathryn@epa.gov, 703-305-1243

USE AND USAGE INFORMATION

Table 3 summarizes the use and usage information for triclopyr. Please see the *BEAD Chemical Profile (BCP) for Registration Review: Triclopyr Case* in the registration review docket for more details.

Table 3: Triclopyr Use and Usage Information	
Summary of Use	Triclopyr is a systemic herbicide that belongs to the pyridine carboxylic acid family and it is used as a post-emergence herbicide to control annual and perennial broadleaf weeds and woody plant species in many agricultural and non-agricultural use sites.
Use Sites	Registered agricultural use sites include alfalfa, almonds, apples, asparagus, beans, beech nut, blackberries, brazil nut, cashews, chestnuts, cole crops, citrus trees, conifer release, , corn (field, pop, and sweet), flax, hazelnuts, lentils, macadamia nuts, mint, oats, onions, pastures, peas, pecans, pistachio nuts, potatoes, rice, safflower, sorghum, soybeans, strawberries, sugar beets, sunflower, vegetable crops, walnuts, wheat, and yucca. Registered non-agricultural use sites include agricultural buildings, airports, cabins, camp sites, canals, Christmas tree plantings, domestic dwellings, patios, fencerows, forest lands, industrial sites, ornamental woody plants, ornamental lawns, ornamental turf, ornamental trees, farm buildings, aquatic areas, wetlands, rights-of-way, and recreational areas.
Summary of Usage	The major uses include pasture and hay with minor use in orchards or vineyards.
Formulation Type(s)	Soluble concentrate, emulsifiable concentrate, liquid (pressurized and ready-to-use), granular, wettable powder, and pelleted.
Application Method(s)	Ground (granular) application, tree trunk or stump injection, bark treatment, foliar spray, soil injection, and aerial applications.

Table 3: Triclopyr Use and Usage Information	
Technical Registrant(s)	Nufarm Limited; Albaugh, Inc.; Dow AgroSciences, LLC.; Repar Crop; Celsius Property
No. of Registrations	142 Section 3 products[5]; 9 Section 24(c) Special Local Needs (SLNs) products.
Restricted Use	No

Guidance for Commenters: Additional areas of *use and usage related information* requested for this registration review, and of particular interest to EPA, are described below.

- Certain triclopyr labels are unclear with respect to application parameters such as the size of the treated area, the extent of a treated "spot," retreatment intervals, or maximum annual application rates. Without further information, EPA expects to use conservative assumptions to approximate these parameters in order to conduct a quantitative risk assessment. However, the Agency will work with registrants to clarify information on triclopyr product labels, especially the maximum annual application rates for non-agricultural uses including golf courses, turf, and ornamental lawns.
- Confirmation of the following label information: sites of application; formulations; application methods and equipment; maximum application rates; frequency of application, application intervals, and maximum number of applications per season; and geographic limitations on use.
- Use distribution (*e.g.*, acreage and geographical distribution of relevant use sites).
- Median and 90th percentile reported use rates (lbs ai/A) from usage data – national, state, and county.
- Typical application timing (date of first application and application intervals) – national, state, and county.
- Usage/use information for non-agricultural uses.
- Typical application interval (days).
- State or local use restrictions.
- Foreign technical registrants not listed above who supply technical triclopyr to the U.S. market.

ANTICIPATED RISK ASSESSMENTS FOR REGISTRATION REVIEW

The most recent quantitative human health risk assessment was performed in 2002 for a new use request on aquatic sites. The most recent ecological and environmental fate risk assessment was completed in 2002 for the same reason. Findings and conclusions from these risk assessments are summarized in:

- *Registration Review; Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Triclopyr, Triclopyr Triethylamine Salt, and Triclopyr Butoxyethyl Ester*
- *Triclopyr; Triclopyr, Triethylamine Salt (TEA), and Triclopyr Butoxyethyl Ester (BEE). Human Health Assessment Scoping Document in Support of Registration Review.*

[5] Section 3 product labels can be obtained from the Pesticide Product Label System (PPLS) website (http://oaspub.epa.gov/pestlabl/ppls.home).

During registration review, the Agency anticipates the need to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of triclopyr. For human health, EPA anticipates the need to conduct revised dietary, residential, occupational and aggregate risk assessments during registration review. If toxicological endpoints or points of departure are revised based on the data that are anticipated to be required for registration review, they will be considered in the new assessments, as well as any changes to the standard operating procedures or default exposure assumptions.

Table 4 below summarizes the anticipated registration review risk assessments based on the Preliminary Problem Formulation and Human Health Assessment Scoping Document.

Table 4: Anticipated Risk Assessments for the Triclopyr Registration Review

Type of Risk Assessment	Conduct?	Notes
Ecological and Environmental Fate		
Comprehensive ecological (species to be assessed include terrestrial and aquatic organisms), including endangered species	Y	
Incidents	Will check for updates	For a discussion of reported ecological incidents for triclopyr, see page 33 of the Preliminary Problem Formulation.
Human Health		
Dietary		
Food	Y	
Drinking water	Y	
Occupational		
Handlers (mixers, loaders, applicators)	Y	
Post-application	Y	
Residential		
Handlers	Y	
Post-application	Y	
Other		
Aggregate	Y	Evaluates the combined risk from dietary and residential exposures.
Cumulative	N	Triclopyr has not been identified as a member of a cumulative group that shares a common mechanism of toxicity.
Tolerances	Y	During registration review, the Agency will evaluate the need to harmonize tolerances with Canadian MRLs and the need to update the current tolerance expressions.
Incidents	Will check for updates	For a discussion of reported human incidents for triclopyr, see page 13 of the Human Health Assessment Scoping Document and the *Triclopyr, salts and esters: Tier I Review of Human Incidents*.

Guidance for Commenters: Additional *ecological information* requested for this registration review, and of particular interest to EPA, is described below.

- Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
- Water quality monitoring data (see Appendix for further details).

TIMELINE

EPA has created the following estimated timeline for the completion of the triclopyr registration review in Table 5 below.

Table 5: Projected Triclopyr Registration Review Timeline

Activities	Estimated Date
Opening the Docket	
Open Docket and 60-day Public Comment Period	2014 – December
Close Public Comment	2015 – February
Case Development	
Final Work Plan	2015 – May
Issue DCI	2015 July – Sept.
Data Submission	2017 July – Sept.
60-day Public Comment Period for Draft Risk Assessments[6]	2019 Jan. – March
Registration Review Decision	
60-day Public Comment Period for Proposed Registration Review Decision	2019 Oct. – Dec.
Registration Review Decision and Begin Post-Decision Follow-up	2020
Total (years)	6

NEXT STEPS

After the 60-day public comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for the registration review of triclopyr.

[6] The regulations governing Registration Review generally require the Agency to provide a public comment period of at least 30 calendar days for draft risk assessments; see 40 CFR Part 155.53(c). For conventional pesticides, the Agency plans to provide a 60 calendar day public comment period generally for draft risk assessments.

Appendix – Additional Areas Considered in the Triclopyr Registration Review

PUBLIC COMMENTS AND FEEDBACK:

Guidance for Commenters: The areas below highlight topics of special interest to the Agency where your comments, data submissions, or reference to sources of additional information could be of particular use.

Trade Irritants:

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. The Agency will work to harmonize tolerances and international maximum residue limits (MRLs) and may modify tolerance levels to do so, when possible. **Growers and other stakeholders are asked to comment** on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality:

Triclopyr is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.[7] In addition, no Total Maximum Daily Loads (TMDL) have been developed for triclopyr.[8] More information on impaired water bodies and TMDLs can be found at the Agency's website.[9] **The Agency invites submission of water quality data for this pesticide.** To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*[10] in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Triclopyr is identified as a cause of impairment, as defined under section 303(d) of the Clean Water Act, for one water body in California, based on information provided at EPA's website.[11] In addition, Total Maximum Daily Loads (TMDL) have been developed for triclopyr in two impaired water bodies in Alabama and one in Louisiana, based on information provided at the website.[12] More information on impaired water bodies and TMDLs can be found at EPA's website.[13] **The Agency invites submission of water quality data for this pesticide.** To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality*

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[7] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

[8] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

[9] http://www.epa.gov/owow/tmdl/

[10] http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

[11] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

[12] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

[13] http://www.epa.gov/owow/tmdl/

Data in OPP's Registration Review Risk Assessment and Management Process[14] in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice:

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to triclopyr compared to the general population. **Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.**

ENDANGERED SPECIES:

A risk assessment that supports a complete endangered species determination has not been conducted for triclopyr. The ecological risk assessment planned during registration review will allow the Agency to determine whether use of triclopyr has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

A previous endangered species assessment for the California red-legged frog was conducted for triclopyr in October 2009.

ENDOCRINE DISRUPTOR SCREENING PROGRAM:

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision for triclopyr, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), triclopyr is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator

[14] http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[15] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[16]

HUMAN STUDIES:

Occupational and Residential

Past triclopyr risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED), the Agricultural Reentry Task Force (ARTF) Database, and the Outdoor Residential Exposure Task Force (ORETF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

[15] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

[16] http://www.epa.gov/endo/